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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,965	12/13/2001	Robert J. Crowley	10121/04903	4630

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EXAMINER	
LAMPRECHT, JOEL	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/022,965	CROWLEY, ROBERT J.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-51, and 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahadevan-Jansen et al in view of Anidjar et al (ULIAD between Malignant and normal Urothelial Cells and Tissues). Mahadevan-Jansen et al disclose a spectrometer device comprising a distal end with light emitting portion (Col 1 Line 35-55, Col 7 Line 5-454), a light detector (Col 13 Line 25-65), an interventional device (Col 6 Line 22-48), a bandpass filter associated with the light detector (Fig 6, Col 12 Line 20-Col 13 line 27), a light source (Col 5 Line 45 – Col 6 Line 15), a lens (Col 6 Line 5-45), the filter as a property of Raman spectroscopy methods (Col 7 Line 5-65), a substrate for disposing the light emitter and detector (Col 6 Line 15-32), a modulator and mirror disposed on the surfaces of the same substrate for receiving light from the light source (Col 6 Line 65- Col 7 Line 25, Col 7 Line 35-45, Table 1, Figure 5), a substantially transparent window (Col 4 Line 5-30), an optical device including a lens (Col 12 Line 40 - Col 13 Line 20), filter (Col 12 Line 40 – Col 13 Line 2), mirror (Col 12 line 40 – Col 13 Line 2, and a hologram (Col 13 Line 3-20). Mahadevan-Jansen et al also disclose connecting the spectrometer to a power source (Table 1, Col 13 – Col 14), measuring

optical properties of light from tissue (Col 7 Line 65 – Col 9 Line 57), specifically for characterizing tissue.

Mahadevan-Jansen et al do not teach the use of a UV light range, rather they stay in the IR spectrum.

Attention is paid to the secondary reference by Anidjar, which teaches the use of a UV-spectrum evaluation of spectroscopy using a multifiber catheter (Page 337, Column 1), filters around the UV range (Page 337, Column 1) and cellular tissues to perform an in vitro study of diagnostic capability of spectroscopy for urothelial tumor diagnosis (Page 335-337). It would have been obvious to one or ordinary skill in the art to have adapted the cellular-level in vitro system of Anidjar et al into the in vivo system of Mahadevan-Jansen et al for the purpose of facilitating real-time early detection of urothelial CIS (Page 339).

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mahadevan-Jansen et al in view of Anidjar et al (ULIAD between Malignant and normal Urothelial Cells and Tissues) as applied to claim 51 above, and in further view of Vari (5,503,559).

Mahadevan-Jansen et al in view of Anidjar et al disclose all that is listed above, but fail to mention the production of the window from polystyrene, polycarbonate, or methyl-methacrylate; rather they teach using a transparent Teflon window for the window material.

Attention is directed to the secondary reference by Vari, which teaches the use of PMMA, polystyrene and other silica-core fibers to allow for the transmission of UV light

(Col 10 Line 5-50). It would have been obvious to one having ordinary skill in the art at the time of the invention to have constructed the window out of PMMA or polystyrene instead of Teflon to allow for UV light transmission through the windowed section of the miniature spectrometer disclosed by Mahadevan-Jansen et al in view of Anidjar as Teflon and quartz envelopes also allow UV light transmission.

Response to Arguments

Applicant's arguments filed 12/24/08 have been fully considered but they are not persuasive. Regarding Applicant's argument that Anidjar doesn't not disclose providing light exclusively in the UV wavelength spectrum, Examiner respectfully disagrees. As well noted in legal precedent, the requirement for a system to correctly render system claims either unpatentable or anticipate those claims relies on the capability of the system to provide the same function or components of the system which is claimed (See MPEP 7.37.09). The system of Anidjar, as recited on pages 336-337 (Section 2.2) the excitation light and corresponding filters for the 308nm and 337nm excitations both lie precisely within the constraints of the instant application as claimed. Furthermore, page 336, column 2, paragraph 2 states that "A bundle composed of 6 excitation and 13 detection silica fibers allowed the use of any excitation wavelength". This, in conjunction with the filters disclosed on the next page constitutes the necessary components to be capable of transmitting only excitation wavelengths within the UV spectrum. Furthermore, and in regard to the further argument that it would be counter intuitive to use only UV light as Applicant has argued that Anidjar is only "seeking to find

the optimal fluorescence intensity", Examiner submits that page 336 Col 1 Paragraph 3 recites that 308nm is an ideal excitation wavelength for one of their inquiries. 308nm lies solely in the UV spectrum. Regarding the argument that Anidjar does not disclose an in vivo method, Examiner agrees with applicant, but that was not the implication of the argument. The implication was that the methods of Anidjar constitute those imaging techniques that can (and provide the motivation) be used within an in vivo method (See P336 Col 1 Paragraph 3, final sentence. The in vivo method being relied upon is that of Mahadevan-Jansen et al, as disclosed within the previous office actions. The imaging components and capabilities from Anidjar are being relied upon within the invention of Mahadevan-Jansen et al, not the other way around. Finally, regarding the argument that Mahadevan does not disclose a spectrometer device with an intervention device, Examiner respectfully disagrees with this assessment of the reference. A specific citation of the interventional device is found on Col 6 Line 22-48 of the Mahadevan-Jansen et al reference including a probe casing, an interventional device designed to carry the spectroscopic components. Furthermore, the Disclosure from Col 5 Line 59-Col 6 Line 65 includes the following recitations which clearly show that the device as taught by Mahadevan is indeed designed for In vivo use:

1. Raman Spectroscopy Probe for In vivo Use.

2. For cervical applications, the stiff section of the probe must be at least 13.5 cm, preferably 20 cm, so that it can be advanced through the speculum to the cervix.

3. Importantly, the probe is small enough to pass inside body cavities such as the vagina, rectum, mouth or a surgically-created cavity.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/BRIAN CASLER/

Supervisory Patent Examiner, Art Unit 3737